

REMARKS

This RCE is filed in lieu of an Appeal Brief further to the Notice of Appeal that was filed on April 11, 2008. Applicants submit herewith preliminary amendments to the claims and remarks to the rejections raised by the Examiner in the outstanding Final Office Action dated December 27, 2007.

Claim Status

Claim 21 has been amended to improve clarity. As amended, claim 21 recites a biological sample comprising a nucleotide sequence which is or is complementary to a sequence selected from the group consisting of SEQ ID NO:1 and SEQ ID NO:2, wherein the nucleotide sequence is detectable in the sample using a nucleic acid amplification or nucleic acid hybridization method.

Claims 22 and 29 have been amended to correct a typographic error as well as to improve clarity. As amended, claims 22 and 29 recite the ATCC deposit number of “PTA-2605” instead of “PTO-2506” or “PTA-2506”. Support for such amendment is found at page 24, line 10-14 of the instant specification as well as in the ATCC deposit receipt, a copy of which was previously submitted along with Applicants’ response of October 18, 2007.

Claim 23 has been amended to further characterize that the claimed biological sample is a DNA sample extracted from the corn event MON863. Support for such amendment is found at page 13, lines 20-21; and page 22, line 24 of the instant specification.

Claims 23 and 24 have further been amended to reflect proper antecedent bases.

Claims 25 and 26 have been amended to improve clarity.

Claim 27 has been amended to characterize that the corn event MON863 has seed deposited with American Type Culture Collection (ATCC) with Accession No. PTA-2605.

Support for such amendment is clearly found at page 24, lines 10-14 as well as in claim 29 as originally filed.

Claim 43 has been amended to improve clarity as well as to correct a typographic error, i.e., removing the space between the letters “T” and “D” when referring to the sequence identifier.

Applicant respectfully submits that the foregoing amendments do not introduce any new matter to the application as originally filed. With the present amendments, claims 21-31 and 43 are currently pending.

Claim Rejection – 35 U.S.C. §102

Claims 21-22 and 29-31 and 43 remain rejected under 35 USC §102(e) as allegedly being anticipated by Pershing et al (2003, US Patent No. 6,551,962; “**Pershing**”). Applicants respectfully traverse this rejection.

Pershing simply describes corn transformation event MON863 as containing a modified sequence encoding a Cry3Bb.11098 variant protein. **Pershing** does not disclose any sequences that are diagnostic for the MON863 event. In particular, **Pershing** does not disclose the junction sequences of SEQ ID NOs:1 and 2 or the amplicon sequences of SEQ ID NOs:3 and 4 that are unique for the MON863 event. Neither does **Pershing** provide the accession number for the deposit of the MON863 event, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination, or the name and address of the depository as argued in Applicants’ previous response of October 18, 2007.

Without knowing the diagnostic structural sequences of the MON863 event, a skilled artisan would not know how to identify or detect such event. The information provided by **Pershing** that MON863 contains a modified sequence encoding a Cry3Bb.11098 variant with

reference to WO 99/31248 does not provide the skilled artisan with the knowledge of the relative position of the nucleotide sequence encoding the Cry3Bb.11098 variant within the corn genome. That is, the position where the nucleotide sequence is inserted within the corn genome is not known from the teaching of **Pershing**. Since the position of the nucleotide sequence encoding the Cry3Bb.11098 variant was not known, the technical knowledge of the MON863 event sufficient to enable a skilled artisan to identify the claimed junction sequences was not known and hence, the subject matters of the claimed invention could not have been arrived at without the disclosure of the present invention.

The claimed junction sequences are unique and specific for the MON863 insertion. These sequences are specific for and result from the particular insertion site of the Cry3 variant expression vector pMON25097. Mere disclosure of **Pershing** that corn event MON863 contains a modified sequence encoding a Cry3Bb.11098 variant does not constitute the technical knowledge of the subject matter sufficient to arrive at the present invention.

Additionally, each transgenic event is unique, which involves unique junction or amplicon sequences sufficient for characterizing the event. The present invention discloses, for the first time, the junction sequences SEQ ID NOs:1 and 2 as well as the amplicon sequences SEQ ID NOs:3 and 4 (which comprise the junction sequences of SEQ ID NOs:1 and 2, respectively) that are unique for the MON863 event and therefore, provides an ability, for the first time, to specifically detect the particular event of MON863 in a corn sample. **Pershing** does not provide the technical knowledge of the MON863 event, let alone an ability to specifically detect such event in a corn sample.

Furthermore, as previously argued and herein reiterated, **Pershing** does not enable the subject matter claimed in the instant application. Rather, **Pershing** mentions multiple events without providing any specific technical features of the events. Also, the MON863 event was

not commercially available at the time of **Pershing's** filing. Absent commercial availability of the MON863 event at the time of filing or any disclosure on biological deposit information of the MON863 event, **Pershing** is not enabled for the MON863 event.

On page 3 of the Final Office Action, the Examiner states that Applicants provided no evidence that MON863 was not available and that the enablement rejection could have been overcome by pointing out availability rather than making a deposit. Applicants argue that the burden is on the Examiner to provide evidence that MON863 was publicly available at the time of **Pershing's** filing. However, the Examiner has not provided any such evidence; rather, assumed that MON863 was available only because **Pershing** mentions MON863. But in fact the only availability of the MON863 event would be through the deposit at the time of **Pershing's** filing, which information was not disclosed by **Pershing** as discussed above.

Additionally, Applicants note that the MON863 event is not claimed in **Pershing**, or involved in the claims of **Pershing**. Enablement is only associated with the claimed subject matters. Since it does not claim the MON863 event or subject matters that are associated with the event, **Pershing** does not need to provide any enablement for the MON863 event. And indeed, **Pershing** provides no enablement for the MON863 event.

As presently amended, instant claims 21-22, 29-31 and 43 clearly refer to the junction sequence of SEQ ID NO:1 or 2 that is diagnostic for the MON863 event, or refer to the ATCC deposit information, which subject matters are not disclosed in **Pershing** as discussed above. As such, **Pershing** does not anticipate the present invention as claimed. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C §102(e) be withdrawn.

Claim Rejection – 35 U.S.C. §103

Claims 21-31 and 43 remain rejected under 35 USC §103(a) as allegedly being unpatentable over **Pershing**. Applicants respectfully traverse this rejection.

As discussed above, **Pershing** simply discloses MON863 as containing a modified sequence encoding a Cry3Bb.11098 variant. **Pershing** does not render obvious the present invention as claimed because: (1) the mere disclosure of the MON863 event as containing a sequence encoding a Cry3Bb.11098 variant is devoid of any technical knowledge that specifically characterizes the event. Without any disclosure of the unique structural features capable of being used for identifying the MON863 event, one of ordinary skill in the art would not be able to practice the claims of the present invention; and (2) each transgenic event is unique, which involves unique junction or amplicon sequences sufficient for characterizing the event. The present invention discloses, for the first time, the junction sequences SEQ ID NOs:1 and 2 as well as the amplicon sequences SEQ ID NOs:3 and 4 and therefore, provides an ability, for the first time, to specifically detect the particular event of MON863 in a corn sample. **Pershing** does not provide the technical knowledge of the MON863 event, let alone an ability to specifically detect such event in a corn sample.

Additionally, Applicants submit that molecular characterizations of transgenic events are not straight forward. In fact, page 2 of the instant specification describes the following:

For this reason, it is often necessary to screen a large number of events in order to identify an event characterized by optimal expression of an introduced gene of interest. For example, it has been observed in plants and in other organisms that there may be a wide variation in levels of expression of an introduced gene among events. There may also be differences in spatial or temporal patterns of expression, for example, differences in the relative expression of a transgene in various plant tissues, that may not correspond to the patterns expected from transcriptional regulatory elements present in the introduced gene construct. For this reason, it is common to produce hundreds to thousands of different events

and screen those events for a single event that has desired transgene expression levels and patterns for commercial purposes. An event that has desired levels or patterns of transgene expression is useful for introgressing the transgene into other genetic backgrounds by sexual outcrossing using conventional breeding methods. Progeny of such crosses maintain the transgene expression characteristics of the original transformant. This strategy is used to ensure reliable gene expression in a number of varieties that are well adapted to local growing conditions. (Emphasis added) *Id.*

The MON863 event was selected from a large number of insertion events based on a number of different evaluations including (1) characterization at a molecular level for the purpose of determining whether one or more Cry3 coding sequences were introduced into the genome during the transformation process; (2) evaluation of the molecular structure of the inserted DNA for its intactness compared to the sequence present in the plasmid containing the DNA intended for insertion into the plant genome; (3) detection of presence or absence of any undesirable segments arising from the backbone of the plasmid; as well as (4) conduction of field studies, which include yield trials and bioassays. The particular MON863 event, so elected, was proven to be commercially significant with a higher corn yield, more efficacious pest control (specifically, conferring resistance to insect infestation by Coleopteran species), and a decrease in the contribution of physical activities a farmer growing this particular transgenic event would need to apply in order to achieve a significant yield advantage over other varieties of corn.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present invention as claimed are not rendered obvious by **Pershing**. As such, the rejection of the instant claims under 35 USC §103(a) should be withdrawn.

This RCE is filed concurrently with a petition for a 5-month extension of time. The Commissioner is authorized to charge Deposit Account No. 08-3038/11899.0262.PCUS00 for the RCE filing fee (\$810) and extension fee (\$2,350). Should any additional fees be required for any reason in connection with this paper, the Commissioner is authorized to deduct such fees from the same deposit account.

Respectfully submitted,

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